K082449



## Section 8
## SPECIAL 510 (k) SUMMARY

SEP 25 2008

Applicant: Bisco, Inc.
1100 W. Irving Park Road
Schaumburg IL, 60193
Contact Person: Michelle Schiltz-Taing
Tel: 847-534-6000
Fax: 847-534-6111
Date Prepared: August 22, 2008

Trade Name: **BisCem**
Common Name: Luting Cement
Classification/Name: Material, Dental Cement
**Class II per 21 CFR 872.3275**

**Description of Applicant Device:**

**BisCem** is a dual-cured self etching and self adhesive resin cement. It is a self-adhesive cement since it bonds to composite, metal, silanated porcelain and tooth structure without applying any adhesive. No etching step is required to bond to dentin or enamel. With its dual syringe system, **BisCem** can be self cured by simply mixing paste **A** and paste **B** or cured by light after mixing paste **A** and paste **B**. Using a mixing tip, the cement could be dispensed to the working area directly. It is intended for use as a luting cement. Due to the unique chemistry of BisCem, refrigeration is necessary when not in use. Allow refrigerated **BisCem** to reach room temperature before use.

**Intended uses of Applicant Device:**

The modified formula is a dual-cure radiopaque dental cement designed to be used as a luting cement. Its physical properties are similar to the predicate device and there has been no change in the intended use.

**Predicate Devices**: BisCem cleared under (K060701) dated May 15, 2006.

**Significant Performance Characteristics:**

| | **BisCem** | **Modified** |
|---|---|---|
| Intended use | Luting cement | Luting cement |
| Chemical composite | Dual-cured (self/light) dental glass filled, resin modified glass ionomer cement | Dual-cured (self/light) dental glass filled, resin cement |
| Mechanical /physical properties | Low viscosity, dispensable composite | Low viscosity, dispensable composite |

Side by side comparisons clearly demonstrate that the applicant device is substantially equivalent to the legally marketed device. It is concluded that the information supplied in this submission has proven the safety and efficacy of this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2008

Ms. Michelle Schiltz-Taing
Regulatory Affairs Coordinator
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K082449
Trade/Device Name: BISCEM
Regulation Number: 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: August 22, 2008
Received: September 5, 2008

Dear Ms. Schiltz-Taing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K K082449

Device Name: BISCEM

Indications for Use:

1. Luting metal crowns, bridges, inlay, and onlays including porcelain-fused-to-metal and composite-to-metal varieties;
2. Luting resin crowns, bridges, inlays, onlays and veneers;
3. Luting metal or non-metal/fiber posts;
4. Luting orthodontic appliances;
5. Luting porcelain inlays, onlays, crowns, and veneers (includes alumina and zirconia).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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